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# Kirschman

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# (54) OFFSET MULTIAXIAL OR POLYAXIAL SCREW, SYSTEM AND ASSEMBLY

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## Related U.S. Application Data

- (63) Continuation of application No. 13/214,428, filed on Aug. 22, 2011, now Pat. No. 8,480,714, which is a continuation of application No. 11/960,119, filed on Dec. 19, 2007, now Pat. No. 8,029,539.
- (51) **Int. Cl. A61B 17/70** (2006.01) **A61B 17/86** (2006.01)
- (52) **U.S. Cl.**

(58) Field of Classification Search

USPC ....... 606/246–248, 251, 253, 257, 264–272, 606/301, 305, 306, 308, 320; 411/398; 280/86.753

See application file for complete search history.

# (56) References Cited

### U.S. PATENT DOCUMENTS

483,342 A 9/1892 Bolte 900,717 A 10/1908 Feaster 2,344,381 A 3/1944 Young 3,019,504 A 2/1962 Castagliuolo 3,648,691 A 3/1972 Lumb et al. (Continued)

### FOREIGN PATENT DOCUMENTS

DE 3219575 12/1983 DE 3639810 5/1988 (Continued)

### OTHER PUBLICATIONS

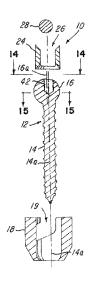
Expedium Spine System, DePuy Spine; Aug. 2004; Raynham, MA 02767.

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# (57) ABSTRACT

A capless multiaxial screw fixation assembly, including a screw having a threaded portion and a screw head portion positioned at one end thereof and a retainer having a first end, a second end opposite the first end, and a bore for receiving the screw threaded portion so that the screw head portion is seated therein. At least one of the screw and the retainer is configured such that the retainer is able to pivot about the screw head portion in a non-symmetrical manner.

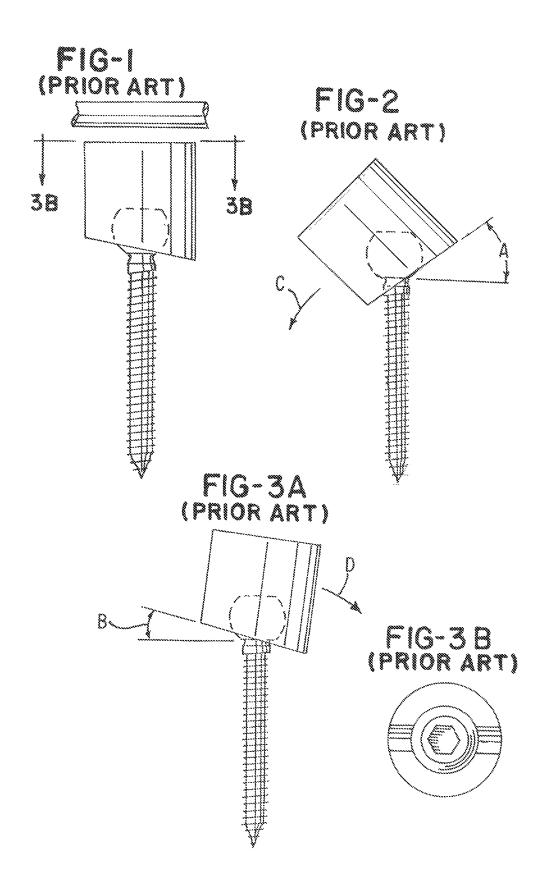
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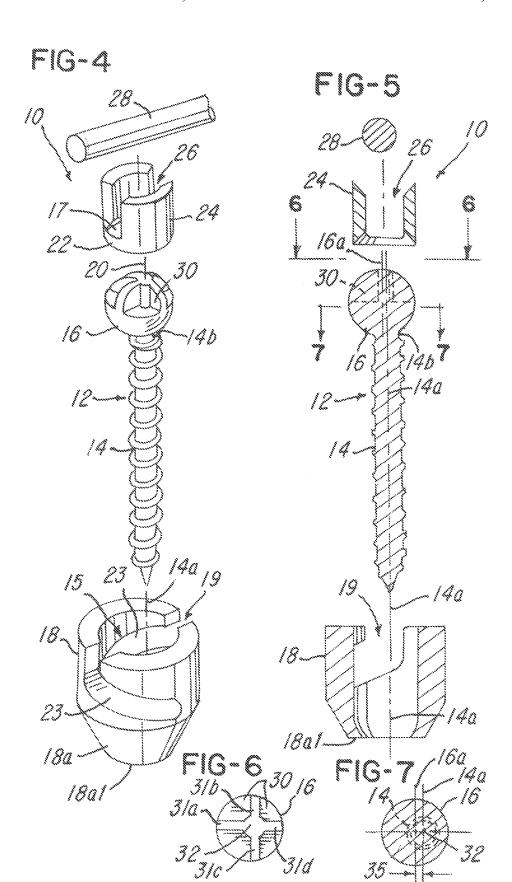


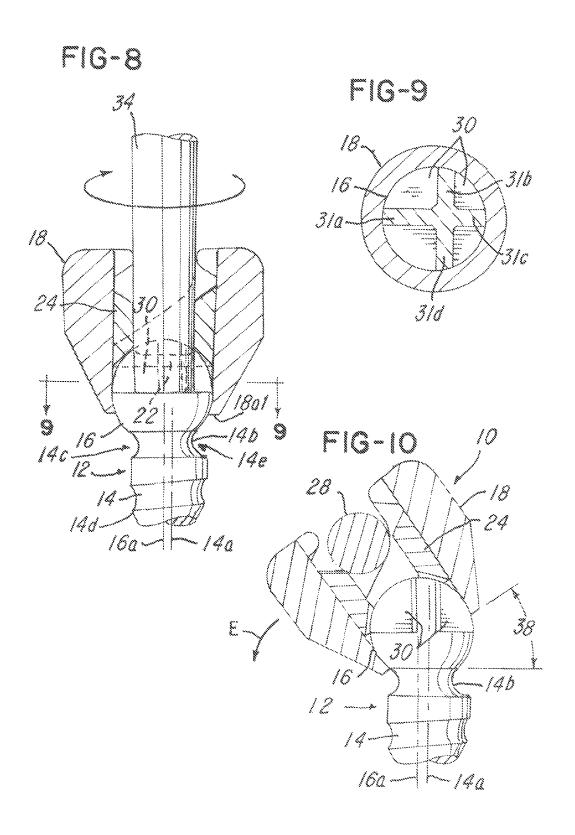
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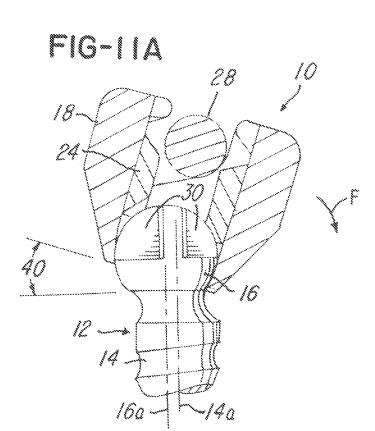
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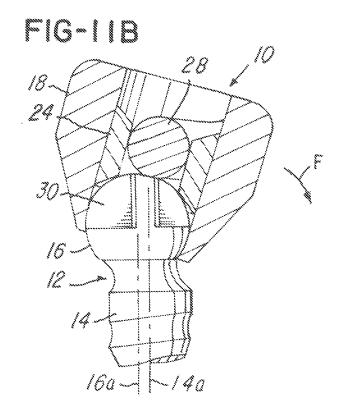
(56)		Referen	ces Cited		,911 A		Sherman et al.
	*** **	U.S. PATENT DOCUMENTS			,350 A		Sherman et al.
	U.S.	PATENT	DOCUMENTS		,286 A ,145 A		Sherman et al. Morrison et al.
2.75		0/1050	77'11 7		,143 A ,004 B2		Barker et al.
	2,203 A	8/1973			,829 B1		Bono et al.
	5,936 A	4/1975			,433 B2		Glascott
	1,602 A		Rybicki et al.		,117 B2		Bono et al.
	5,744 A		Lewis et al.		,426 B2		Moumene et al.
	9,178 A	5/1981 9/1981			,627 B2		Hawkes et al.
	9,124 A 4,300 A		Bouwman		,655 B2		Warnick
	9,139 A	1/1982			.172 B2		Warnick
	1,259 A		Drummond		.835 B2		Warnick
	4,995 A		Stephens et al.	7,717	,943 B2		Kirschman
	1,580 A	9/1986		7,780	,703 B2	8/2010	Yuan et al.
	1,581 A	9/1986		7,785	,353 B2	8/2010	Sybert
	1,636 A	2/1987		2002/0120	)272 A1	8/2002	Yuan et al.
	8,388 A	3/1987		2004/022:	5289 A1	11/2004	Biedermann et al.
	3,481 A		Howland et al.	2005/0033	3296 A1	2/2005	Bono et al.
	5,199 A	4/1987		2005/017	7154 A1	8/2005	Moumene et al.
	8,809 A		Ulrich et al.	2006/005			Hammer et al.
	5,290 A	9/1987		2006/015:			Warnick 606/61
	9,905 A	1/1988		2006/016		7/2006	Ensign et al.
	3,644 A	8/1988	Webb	2006/016			Hawkes et al.
	1,767 A	9/1988	Steffee	2006/0173			Hawkes et al.
4,80	5,602 A	2/1989	Puno et al.	2006/019:		8/2006	Sybert
4,81	5,453 A	3/1989	Cotrel	2006/023:			Bono et al.
	7,595 A	12/1989	Heinig et al.	2007/0043			Kirschman
4,88	7,596 A		Sherman	2007/0053			Warnick et al.
4,913	3,134 A	4/1990	Luque	2007/0093			Hawkes et al.
4,94	5,458 A	8/1990	Harms et al.	2007/0093			Warnick
	0,269 A		Gaines, Jr.	2007/012:	3862 A1	5/2007	Warnick
	5,562 A	4/1991					
	4,213 A		Asher et al.		FORE	IGN PATE	NT DOCUMENTS
	2,982 A		Harms et al.				
	7,955 A	11/1991		DE	3′	711013	6/1988
	4,049 A		Asher et al.	DE		403231	4/1994
	2,867 A		Harms et al.	EP		128058	12/1984
	3,685 A		Asher et al.	EP		242705	10/1987
	0,171 A	6/1992		$\underline{\mathbf{EP}}$		242708	10/1987
	7,912 A		Ray et al.	EP		190678	3/2002
	9,900 A		Asher et al.	FR		615095	11/1988
	5,680 A	2/1993	Vignaud et al.	FR		624720	6/1989
	3,359 A 0,543 A		Schlapfer	FR		852815	10/2004
	7,678 A		Harms et al.	GB		167228	7/1921
	1,913 A	11/1993		GB		173104	10/1986
	0,431 A		Puno et al.	WO WO		707134	12/1987
	0,325 A		Lahille et al.	WO WO		152758 047555	7/2001 5/2006
	5,323 A 5,237 A		Byrd, III et al.	WO		047333 047707	5/2006
	4,555 A		Puno et al.	WO		047707 047711	5/2006
	4,442 A		Mellinger et al.	WO	2000	UT / / I I	512000
	2,486 A		Craig et al.	* cited by	examin	er	
2,70	-,						











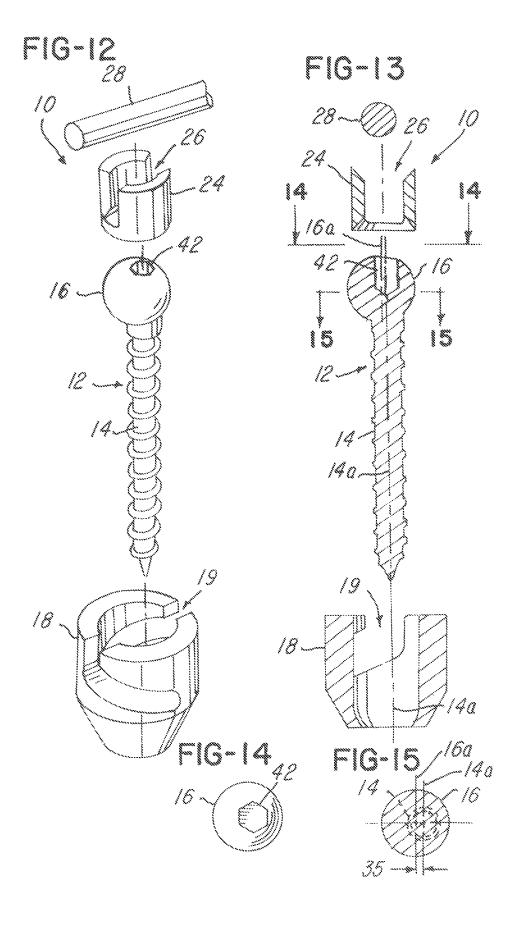


FIG-16

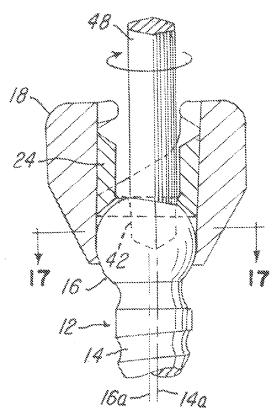
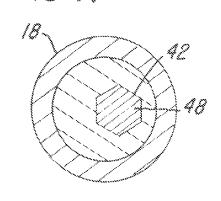


FIG-17



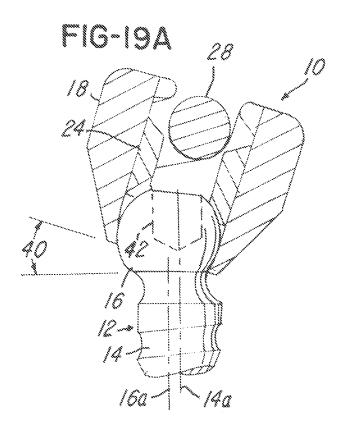
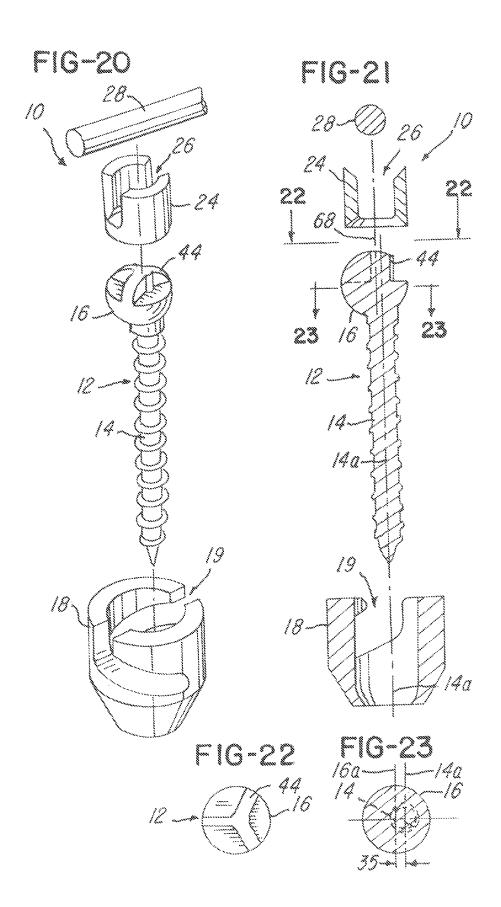


FIG-19B

18 28 10

18 28 16

18 16 160 140



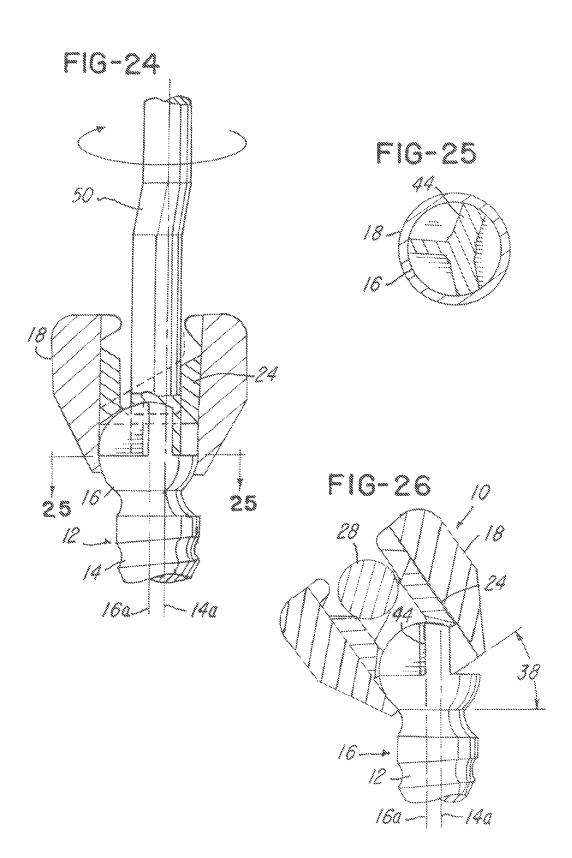


FIG-27A

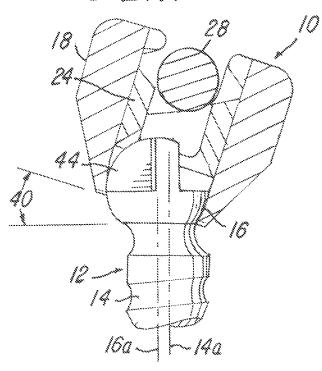
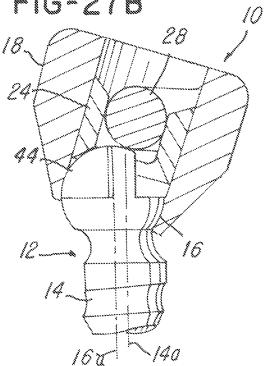
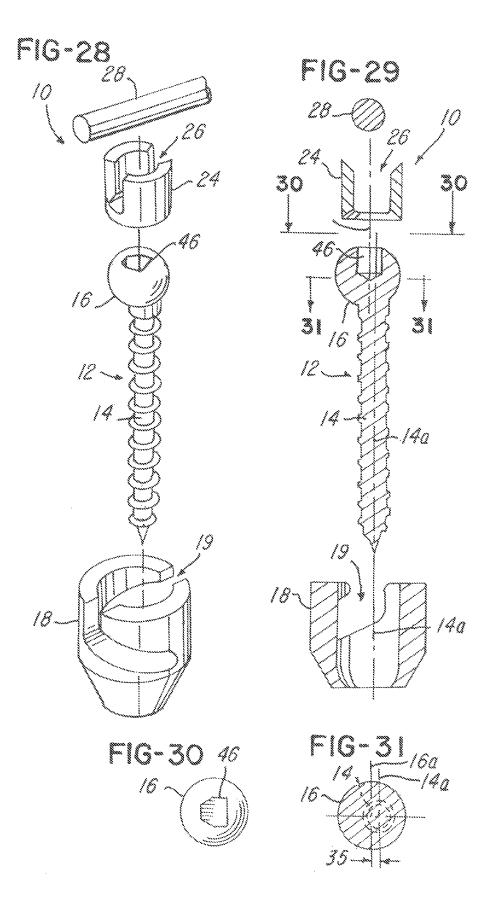


FIG-278





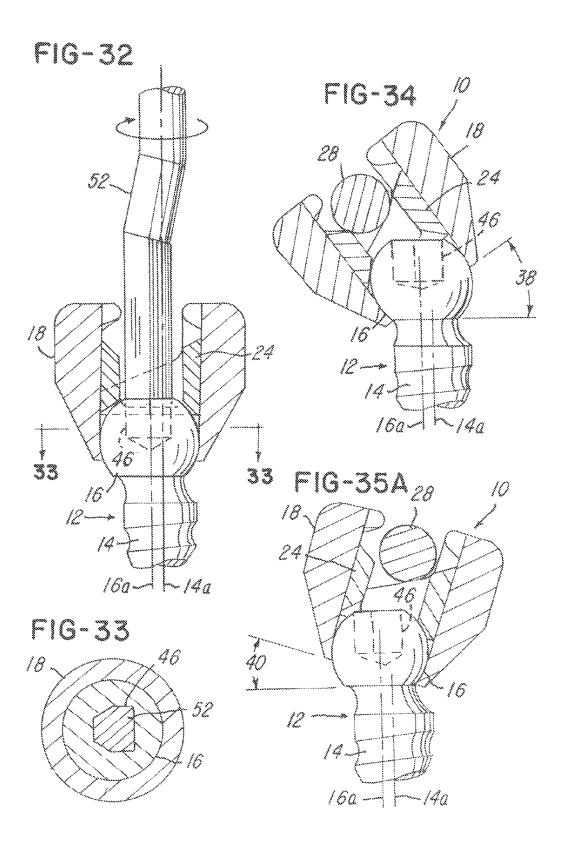
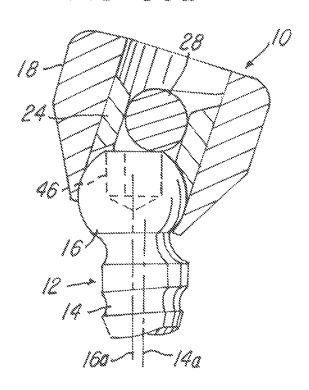
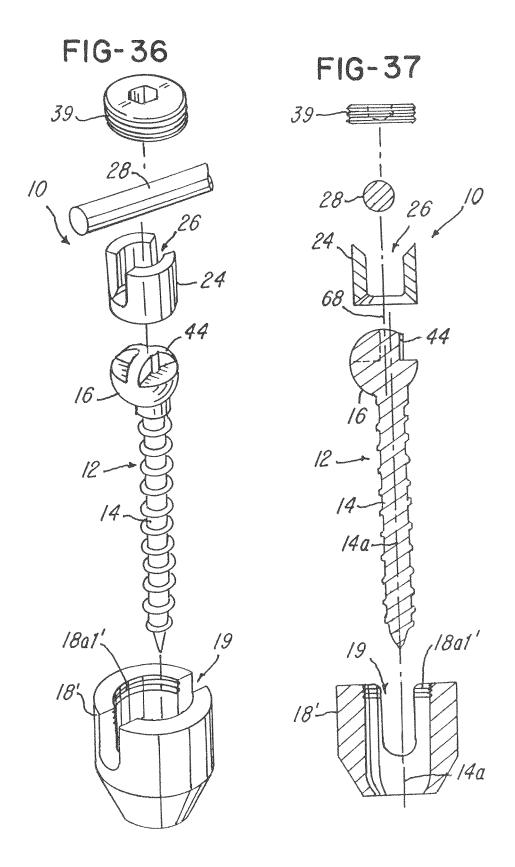
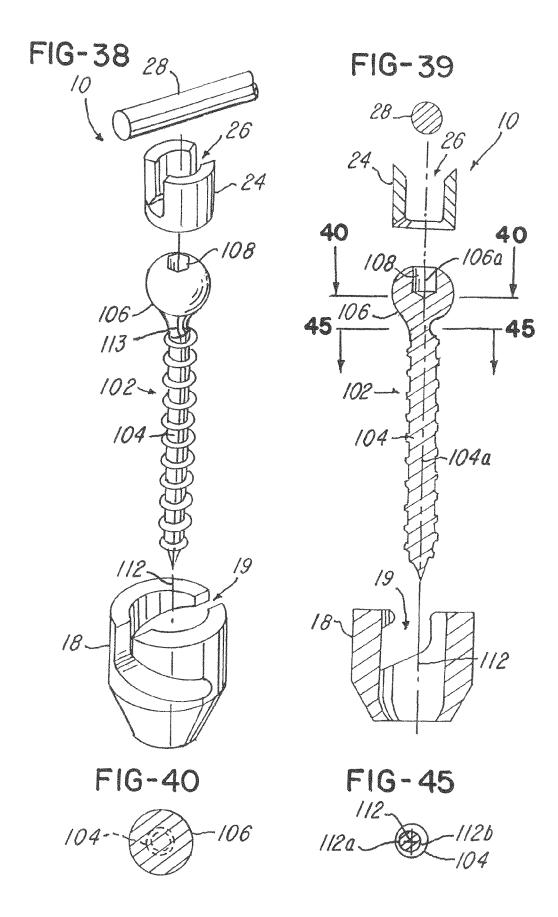
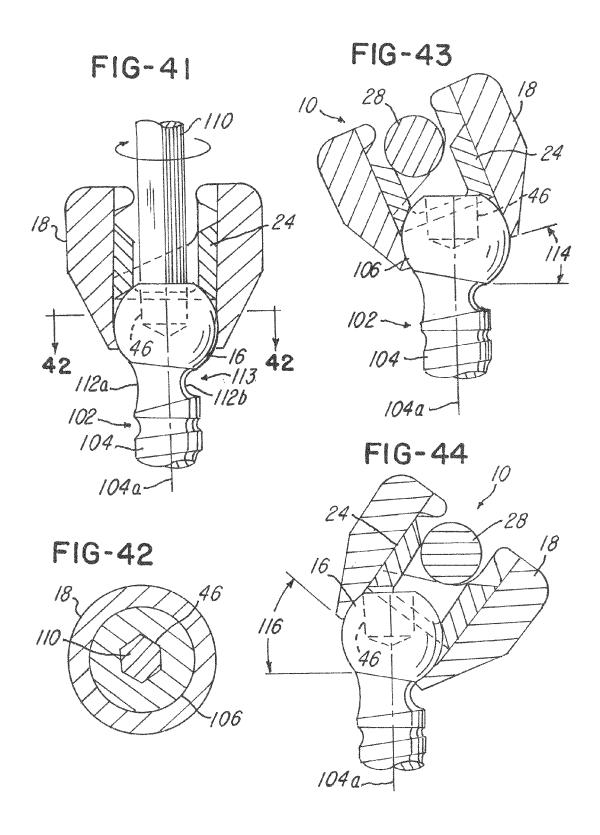


FIG-358









# OFFSET MULTIAXIAL OR POLYAXIAL SCREW, SYSTEM AND ASSEMBLY

### CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. patent application Ser. No. 13/214,428 filed Aug. 22, 2011, which is a continuation of U.S. patent application Ser. No. 11/960,119, filed Dec. 19, 2007, now issued as U.S. Pat. No. 8,029,539, 10 which applications are incorporated herein by reference and made a part hereof.

#### BACKGROUND OF THE INVENTION

### 1. Field of the Invention

The present invention relates generally to a screw having an offset head and to a multiaxial or polyaxial screw for use with a bone fixation system and, in particular, to a multiaxial or polyaxial screw which permits a greater range of pivotabil- 20 ity in at least one direction.

# 2. Description of the Related Art

As is generally known in the art, spinal abnormalities may be correctable using a pair of posterior spinal fixation rods attached to the vertebrae using pedicle screws and the like. In 25 order to provide increased stability and rigidity, especially to resist twisting or the like, the pair of elongated rods often include cross connecting devices. The cross connecting devices typically traverse the spinal column and couple to each of the elongated rods. In other words, the cross connect- 30 ing devices are perpendicular or substantially perpendicular to the spinal column.

In addition, bone screws with a polyaxial head are commonly used in spine surgery today. They are used chiefly in the lumbar spine and screwed into bone (pedicle) posteriorly. 35 The head of the screw is attached to the shaft of the screw. The head of the screw is machined into a ball, and the head may be provided with a receiver or socket into which the ball fits. One typical prior art system further contains a receiver for receiving a separate rod. The rod is fastened to the screw head 40 receiver via a threaded cap. The rod is then fastened to screws placed in adjacent vertebrae thus providing stabilization. The polyaxial head allows the rod to be placed in a variety of angles with respect to the screw allowing conformance to local anatomy.

Exemplary bone screws are disclosed in the following patents: U.S. Pat. No. 5,466,237 to Bird et al.; U.S. Pat. No. 4,946,458 to Harms; U.S. Pat. No. 5,207,678 to Harms et al.; U.S. Pat. No. 5,474,555 to Puno et al.; and U.S. Pat. No. 6,869,433 to Glascott. It will be appreciated from the prior art, 50 however, that multiaxial screws involve the ability to pivot symmetrically or the same amount in each direction. In some instances, it is desired for the retainer to be moved or pivoted about the screw head more in a certain direction than in another, whereby greater maneuverability of the rod attached 55 bly depicted in FIGS. 4-6 taken along line 7-7 in FIG. 5; to the retainer may be accommodated. It was difficult to get a "favorable angle" of the retainer relative to the screw head.

FIGS. 1-3B show a prior art system wherein a retainer having an angled or canted surface that permits movement between a predetermined angle A (FIG. 2) and a different 60 smaller angle B (FIG. 3A) when the retainer is moved between a first direction C and a second direction D, respec-

Thus, it would be desirable for a multiaxial screw assembly to be developed for use with a spinal fixation system which 65 permits non-symmetrical pivoting and that is capable of use with a variety of retainers, including those with non-canted

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surfaces. It would also be desirable for a multiaxial screw assembly to be developed in which simple modification of existing components enables the desired pivoting action.

### SUMMARY OF THE INVENTION

It is therefore, an object of the invention to provide a polyaxial screw having a head that provides a greater range of mobility.

In one aspect, one embodiment comprises a multiaxial screw fixation system, comprising a screw having a threaded portion and a screw head portion positioned at one end thereof and a retainer having a first end, a second end opposite the first end, and a bore for receiving the threaded portion so that the screw head portion may be seated therein, wherein the screw is adapted such that the retainer is able to pivot about the screw head portion in a non-symmetrical manner.

In another aspect, another embodiment comprises a multiaxial screw fixation system, comprising a screw having a threaded portion and a screw head portion positioned at one end thereof and a retainer having a first end, a second end opposite the first end, and a bore for receiving the threaded portion so that the screw head portion may be seated therein, wherein the screw head portion comprises at least one of a partial opening or partial shape that interfaces or connects with a tool, wherein the at least one of the partial opening or the partial shape is offset from an axis of the threaded portion.

These and other objects and advantages of the invention will be apparent from the following description, the accompanying drawings and the appended claims.

# BRIEF DESCRIPTION OF THE OF THE ACCOMPANYING DRAWINGS

FIG. 1 is a front elevation view of a prior art retainer having a centered bottom edge;

FIG. 2 is a front elevation view of a prior art retainer, wherein the retainer associated therewith is shown in a first pivoted position;

FIG. 3A is a front elevation view of the prior art retainer assembly depicted in FIGS. 1 and 2, wherein the retainer associated therewith is shown in a second pivoted position;

FIG. 3B is a top view of the prior art retainer taken along the 45 line **3**B-**3**B in FIG. **1**;

FIG. 4 is an exploded perspective view of the polyaxial screw assembly having an offset head, wherein a compression member and a rod for engagement with the compression member are also shown;

FIG. 5 is an exploded side view of the polyaxial screw assembly depicted in FIG. 4;

FIG. 6 is a top view of the polyaxial screw assembly depicted in FIGS. 4 and 5 taken along line 6-6 in FIG. 5;

FIG. 7 is a top sectional view of the polyaxial screw assem-

FIG. 8 is an enlarged, partial sectional view of the polyaxial screw assembly depicted in FIGS. 4 and 5, wherein a tool is shown as interfacing with a head portion thereof to position it within the retainer;

FIG. 9 is a top sectional view of the polyaxial screw assembly with the head portion thereof positioned within the retainer, as depicted in FIG. 8, taken along line 9-9 of FIG. 8;

FIG. 10 is an enlarged, partial sectional view of the polyaxial screw assembly depicted in FIG. 8, wherein the compression member and rod engaged therewith are included and the retainer has been pivoted to a maximum degree in a first direction;

- FIGS. 11A and 11B are enlarged, partial sectional views of the polyaxial screw assembly depicted in FIG. 8, wherein the compression member and rod in unlocked and locked positions and the retainer has been pivoted to a maximum degree in a second direction:
- FIG. 12 is an exploded perspective view of a polyaxial screw assembly having a first alternative configuration, wherein a compression member and a rod for engagement with the compression member are also shown;
- FIG. 13 is an exploded side view of the polyaxial screw assembly depicted in FIG. 12;
- FIG. 14 is a top view of the polyaxial screw assembly depicted in FIGS. 12 and 13 taken along line 14-14 in FIG. 13,
- FIG. 15 is a top sectional view of the polyaxial screw assembly depicted in FIGS. 12 and 13 taken along line 15-15 in FIG. 13:
- FIG. 16 is an enlarged, partial sectional view of the polyaxial screw assembly depicted in FIGS. 12 and 13, wherein a tool is shown as interfacing with a head portion 20 thereof to position it within the retainer;
- FIG. 17 is a top section view of the polyaxial screw assembly with the head portion thereof positioned within the retainer, as depicted in FIG. 26, taken along line 17-17 of FIG. 16.
- FIG. 18 is an enlarged, partial sectional view of the polyaxial screw assembly depicted in FIG. 16, wherein the compression member and rod engaged therewith are included and the retainer has been pivoted to a maximum degree in a first direction:
- FIGS. 19A and 19B are enlarged, partial sectional views of the polyaxial screw assembly depicted in FIG. 16, wherein the compression member and rod in unlocked and locked positions and the retainer has been pivoted to a maximum degree in a second direction;
- FIG. 20 is an exploded perspective view of a polyaxial screw assembly having a second alternative configuration, wherein a compression member and a rod for engagement with the compression member are also shown;
- FIG. 21 is an exploded side view of the polyaxial screw 40 assembly depicted in FIG. 20;
- FIG. 22 is a top view of the polyaxial screw assembly depicted in FIGS. 20 and 21 taken along line 22-22 in FIG. 21,
- FIG. 23 is a top sectional view of the polyaxial screw assembly depicted in FIGS. 20 and 21 taken along line 23-23 45 in FIG. 21:
- FIG. 24 is an enlarged, partial sectional view of the polyaxial screw assembly depicted in FIGS. 20 and 21, wherein a tool is shown as interfacing with a head portion thereof to position it within the retainer;
- FIG. 25 is a top section view of the polyaxial screw assembly with the head portion thereof positioned within the retainer, as depicted in FIG. 24, taken along line 25-25 of FIG. 24.
- FIG. **26** is an enlarged, partial sectional view of the 55 polyaxial screw assembly depicted in FIG. **24**, wherein the compression member and rod engaged therewith are included and the retainer has been pivoted to a maximum degree in a first direction;
- FIGS. 27A and 27B are enlarged, partial sectional views of 60 the polyaxial screw assembly depicted in FIG. 24, wherein the compression member and rod in unlocked and locked positions;
- FIG. 28 is an exploded perspective view of a polyaxial screw assembly having a third alternative configuration, 65 wherein a compression member and a rod for engagement with the compression member are also shown;

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- FIG. 29 is an exploded side view of the polyaxial screw assembly depicted in FIG. 28;
- FIG. 30 is a top view of the polyaxial screw assembly depicted in FIGS. 28 and 29 taken along line 30-30 in FIG. 29,
- FIG. 31 is a top sectional view of the polyaxial screw assembly depicted in FIGS. 28 and 29 taken along line 31-31 in FIG. 29;
- FIG. 32 is an enlarged, partial sectional view of the polyaxial screw assembly depicted in FIGS. 28 and 29, wherein a tool is shown as interfacing with a head portion thereof to position it within the retainer;
- FIG. 33 is a top sectional view of the polyaxial screw assembly with the head portion thereof positioned within the retainer, as depicted in FIG. 32, taken along line 33-33 of FIG. 32;
- FIG. **34** is an enlarged, partial sectional view of the polyaxial screw assembly depicted in FIG. **32**, wherein the compression member and rod engaged therewith are included and the retainer has been pivoted to a maximum degree in a first direction;
- FIGS. 35A and 35B are enlarged, partial sectional view of the polyaxial screw assembly depicted in FIG. 32, wherein the compression member and rod engaged therewith in unlocked and locked positions;
- FIG. 36 is an exploded view of another embodiment of the invention illustrating the polyaxial screw assembly used in combination with a retainer that utilizes a cap, such as a thread cap;
- FIG. **37** is a sectional exploded view of the embodiment of shown in FIG. **36**;
  - FIG. 38 is a view of another embodiment of the invention wherein a screw head has a common or coaxial axis with the shank:
- FIG. **39** is a sectional view of the embodiment shown in <sup>35</sup> FIG. **38**:
  - FIG. 40 is a sectional view taken along the line 40-40 in FIG. 39;
- FIG. **41** is a fragmentary sectional view of the embodiment shown in FIG. **39** illustrating the use of a tool that becomes of coaxial with the axes and shank;
  - FIG. 42 is a sectional view taken along the line 42-42 in FIG. 41:
  - FIG. 43 is a fragmentary sectional view of the embodiment shown in FIG. 38 illustrating the pivotal movement of the retainer relative to the head, with the retainer being in an unlocked position;
  - FIG. 44 is another fragmentary sectional view of the embodiment shown in FIG. 38 illustrating the pivotal movement of the head in a direction that is different from the direction shown in FIG. 43, but illustrating a greater degree of pivoting; and
  - FIG. **45** is a sectional view of an intermediate portion showing its eccentricity and non-symmetry about an axis.

# DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring now to the drawings in detail, wherein identical numerals indicate the same elements throughout the figures, FIGS. 4-35B depict various embodiments of a multi-axial screw and spinal fixation assembly 10. Spinal fixation assembly 10 includes a screw 12 having a threaded portion 14 and a screw head 16 that preferably has a rounded, arcuate, spherical or curved profile. Spinal fixation assembly 10 further includes a retainer 18, which preferably has a generally cylindrical configuration. In these illustrative embodiments, the retainer 18 is capless, but the retainer 18 could be non-cap-

less, such as is illustrated in FIGS. 36 and 37 below. Although not shown, it will be appreciated that retainer 18 includes an aperture or bore 15 therethrough along a centerline axis 20 (FIG. 4). Accordingly, the bore 15 that receives a threaded portion 14 of the screw 12 until screw head 16 thereof is 5 received adjacent a first end 18a of retainer 18. It will be understood that screw head 16 may be positioned within retainer 18 in any known manner so that multiaxial or polyaxial and relative movement between retainer 18 and screw 12 is permitted. In this way, a user, such as a surgeon or 10 physician, is able to change the polyaxial position of retainer 18 relative to screw 12 in order to adjust an angular position of the retainer or receiving channel 19 and an elongated member or rod, such as rod 28 (FIG. 6), which is received and retained in the retainer 18 at a first end 18a.

Contrary to similar assemblies in the prior art shown in FIGS. 1-3B, screw 12 is configured so that the retainer 18 is able to pivot in a non-symmetrical manner about screw head 16. More specifically, it will be noted from the embodiment shown in FIGS. 10, 11A-11B, 18, 19A-19B, 26, 27A-27B, 34 20 and 35A-35B, that a centerline axis 16a of screw head 16 is offset from a centerline axis 14a of the threaded portion 14. The screw head 16 enables the retainer 18 to pivot by varying degrees in different directions. In this way, implementation of spinal fixation assembly 10 will permit a greater degree of 25 movement of the retainer 18 toward the threaded portion 14, which may be desirable for a given application or case.

In the illustration, the retainer 18 which preferably has a generally cylindrical configuration with helical rod-receiving channels 21 and 23 (FIG. 4) similar to that described in detail 30 in U.S. Patent Application Publication 2007/0043357 A1 to Kirschman U.S. patent application Ser. No. 11/193,523 filed Jul. 29, 2005; U.S. patent application Ser. No. 11/610,698 filed Dec. 14, 2006; and U.S. patent application Ser. No. 11/762,911 filed Jun. 14, 2007, which are also owned by the 35 assignee of the present application and all of which are incorporated by reference and made a part hereof.

It will be appreciated that retainer 18 preferably includes a receiving channel 19 in communication with the helical rod-receiving channels 21 and 23 for engaging an elongated rod or 40 member 28. In one embodiment, the rod 28 may engage directly against the screw head 16.

The spinal fixation assembly 10 may further include a compression member 24 that is received in the bore 15. The compression member 24 comprises a receiving channel 26 45 which is utilized to receive engage rod 28 and which engages the screw head 16.

As mentioned earlier, the screw 12 may be used with a non-capless retainer 18, such as retainer 18' in FIGS. 36 and 37, which utilizes a cap or other means for retaining rod 28 in 50 the retainer.

While a centerline axis 14a through threaded portion 14 of screw 12 remains generally aligned with a centerline axis 16a through retainer 18, it will be appreciated that a centerline axis 16a through screw head 16, however, is generally offset 55 from and not coaxial with centerline axes 14a and 16a. As such, screw head 16 may either be rotated so that centerline axis thereof is at a specified angle relative to centerline axes 14a and 16a or shifted in parallel to such centerline axes 14a and 16a. In either case, it will be understood that screw head 60 16 is not configured or oriented so as to be symmetrical with respect to or about the centerline axes 14a and 16a.

Screw head 16 preferably includes at least one female opening, slot or groove 30 (FIG. 4) so that a corresponding tool 34 is able to interact with screw 12 in order to threadingly screw the screw 12 into spinal bone. The opening 30 to be formed therein for receiving the corresponding tool 34 which

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enables screw 12 to be threaded into and out spinal bone. As best seen in FIGS. 6 and 9, the partial opening is configured as walls 31a, 31b, 31c and 31d that intersect at point 32 and that define recessed areas or slots 30 formed in screw head 16 (i.e., as for a Phillips screw). More specifically, the walls 31a, 31b, 31c and 31d define opening 30 in screw head 16. Note that the intersecting point 32 is aligned with centerline axis 14a of threaded portion 14 or a distance 35 (FIG. 7) from centerline axis 16a. In this way, the tool 34 (FIG. 8) is able to access the screw head 16 and slots 30 and pressure applied thereby is directed along centerline axis 14a.

When screw head 16 is seated properly within retainer 18, as viewed for example in FIGS. 8, 10 and 11, it will be appreciated that the intentional misalignment of screw head 16 and threaded portion 14 creates the ability for retainer 18 (and compression member 24) to pivot non-symmetrically. For example, FIG. 10 depicts the pivoting of retainer 18 about screw head 16 in a first direction E as an angle 38 with a range of, for example, approximately 0°-55°. Similarly, FIG. 11A shows the pivoting of retainer 18 about screw head 16 in a second direction F (opposite the first direction), where an angle 40 has a range of, for example, approximately 0°-55°. Clearly, the maximum amount of movement or pivoting is greater in the first direction E than in the second direction F. This permits a desirable flexibility for the adjustment of rod 28 when secured as part of a spinal fixation assembly.

FIG. 11B shows the rod 28 in a loaded and locked position after the retainer 18 has been pivoted and rotated to the locked position.

It will be understood that the partial opening or partial shape of the screw head 16 and the corresponding tool or driver utilized to interface therewith may take any desirable form. Besides the exemplary slots 30 and tool 34 shown in FIGS. 6, 8 and 9, other possible configurations of the screw head 16 include, but are not limited to a shape adapted to define a hexagonal opening 42 (FIGS. 14 and 17), a "Y" shape 44 (FIGS. 22 and 25), and an opening 46 defined by a plurality of side walls (FIGS. 30 and 33). Of course, corresponding tools 48 (FIG. 16), 50 (FIG. 24) and 52 (FIG. 32) would be utilized therewith, respectively. It will be appreciated that the respective tool may have a linear configuration (as evidenced by tools 34 and 48) or a non-linear configuration (as seen for tools 50 and 52).

Moreover, the embodiments of FIGS. 4-35B illustrate use of the screw 12 with the compression module 17, but it should be understood that the screw 12 may be used with retainers that do not utilize a compression module 17. It should be understood that while the embodiments illustrated in FIGS. 4-35B illustrate the use of the screw 12 with a capless retainer and compression module 17, the screw 12 may be used with non-capless systems. For example, FIGS. 36 and 37 illustrate the use of the screw 12 with a non-capless retainer 18'. In this embodiment, retainer 18' has a threaded interior surface for receiving a threaded cap 39. Of course, the screw 12 may also be used with other types of retainers that utilize other means for retaining the rod in the receiver, and such receivers and securing mechanisms are known to those skilled in the art.

Referring now to FIGS. **38-44**, another embodiment is shown. In this embodiment, those parts that are the same or similar to the part shown in FIGS. **4-35**B are identified with the same part number.

As shown in FIGS. 38 and 39, notice that this embodiment utilizes a screw 102 having a threaded shank 104 and a head 106. The head 106 comprises a female aperture 108 for receiving a tool for screwing the screw 102. In the illustration being described, and as illustrated in FIG. 41, the tool 110 may be a linear tool, without an offset of the type illustrated in

FIG. 24, for example. Notice that in this embodiment, the retainer 18 comprises an axis 112 that is coaxial with the axis 104a of the shank 104. Notice also that the head 106 comprises an axis 106a that is coaxial with both the axis 104a of shank 104 and the axis 112 as illustrated in FIG. 39. This is advantageous in that when the screw 102 is rotatably driven, it may be driven along a common axis which facilitates mounting or screwing the screw 102 into bone.

As best illustrated in FIGS. 38 and 39, notice that the head **106** is integrally secured to the shank **104** by an intermediate <sup>10</sup> or neck portion 113. As shown in FIGS. 41-43 and 44, notice that the neck portion 113 comprises a first surface or area 112a having a relatively large radius and a second surface or area 112b that has a relative small radius as shown. The larger and small radiuses of the surfaces 112a and 112b permit the retainer 18 to be pivoted a plurality of different angles or degrees. For example, FIG. 43 illustrates the retainer 18 pivoting to the left (as viewed in FIG. 43) a predetermined angle 114 as shown. In contrast, notice in FIG. 44, the relatively small radius surface 112b defines an area or intermediate 20portion 113 that permits the retainer 18 to pivot toward the right (as viewed in FIG. 44) a predetermined angle 116 which is greater than the predetermined angle 114 as in at least one area of the intermediate portion 113.

To enable the polyaxial movement, notice in FIG. 41 that <sup>25</sup> the intermediate portion 113 is neither centric nor symmetrical about the axis 104a. Thus, the intermediate portion 113 is eccentric about axis 104a. Notice in FIGS. 38-45 that the radius of curvature is not constant about the axis 104a and generally becomes larger as the radius of curvature moves from the portion or area 112b toward the area 112a, with the area 112a having the largest radius of curvature. Thus, not only is the intermediate portion 113 not symmetrical about the axis 104a, but the radius of curvature changes as well.

This embodiment enables the system of FIGS. **38-45** to <sup>35</sup> enable the retainer **18** to pivot a plurality of angles about the head **106**, with the greatest degree of pivot being realized when the retainer **18** pivots toward the smallest radius of curvature **112***b* and the smallest amount of pivot being achieved when the retainer **18** is pivoted toward the largest radius of curvature **112***a*. Thus, the embodiment of FIGS. **38-45** enables the retainer **18** to pivot a plurality of different angles about the head **106** as shown.

Another advantage of the embodiment illustrated in FIGS. 38-44 is that it enables the use of the tool 110 that is generally linear and that is not offset as illustrated, for example, in the embodiment shown in FIG. 24. This facilitates enabling the tool 110 to become coaxial with the axes of the head 106 and shank 104, as illustrated in FIG. 41, which facilitates rotating the screw 102 and mounting in into bone.

FIG. 42 shows a cross-section of the illustration shown in FIG. 41 illustrating the tool 110 being coaxial with the head 106 as shown.

Note also that an intersection of the screw head **16** to the threaded portion **14** may have a wall **14**b (FIGS. **5** and **8**) that defines an area **14**c that is generally concave and permits a bottom edge **18**a**1** (FIGS. **4**, **5** and **8**) of retainer **18** to move inwardly toward centerline axis **14**a and inside an imaginary plane defined by the outside edge **14**d (FIG. **8**) of at least one thread on the threaded portion **14**.

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Having shown and described the preferred embodiment of the present invention, further adaptations of the capless multiaxial screw can be accomplished by appropriate modifications by one of ordinary skill in the art without departing from the scope of the invention.

While the system and method herein described constitute preferred embodiments of this invention, it is to be understood that the invention is not limited to this precise system and method, and that changes may be made therein without departing from the scope of the invention which is defined in the appended claims.

What is claimed is:

- 1. A multiaxial screw fixation system, comprising:
- (a) a screw having a threaded portion and a screw head portion positioned at one end thereof; and
- (b) a retainer having a first end, a second end opposite said first end, and a bore for receiving said threaded portion so that said screw head portion may be seated therein, said retainer further comprising a retainer rod-receiving channel and having a retainer centerline axis;
- wherein said threaded portion comprises a screw centerline axis, said screw centerline axis being offset from said retainer centerline axis when said screw centerline axis and said retainer centerline axis are parallel;
- wherein said retainer can pivot about said screw head portion a greater degree in a first direction compared to a second direction so that a maximum amount of pivoting in said first direction is greater than in said second direction.
- 2. The multiaxial screw fixation system of claim 1, wherein a tool has an offset for driving said screw.
- 3. The multiaxial screw fixation system of claim 2, wherein said screw head has a partial opening formed therein for receiving a tool.
- **4**. The multiaxial screw fixation system of claim **3**, wherein said partial opening is a hex opening.
- 5. The multiaxial screw fixation system of claim 3 wherein a centerpoint of said partial opening is offset from a second centerline axis of said threaded portion.
- **6**. The multiaxial screw fixation system of claim **1**, wherein a centerpoint of a partial opening is aligned with a first centerline axis of said screw head portion.
- 7. The multiaxial screw fixation system of claim 1, wherein said screw head has a partial shape formed therein for receiving a tool.
- **8**. The multiaxial screw fixation system of claim **7** wherein said partial shape is a Y-shape.
- **9**. The multiaxial screw fixation system of claim **7** wherein a centerpoint of said partial shape is offset from a centerline axis of said threaded portion.
- 10. The multiaxial screw fixation system of claim 7, wherein a centerpoint of said partial shape is aligned with a centerline axis of said screw head portion.
- 11. The multiaxial screw fixation system of claim 1, wherein said screw head portion comprises at least one of a partial opening or partial shape that interfaces or connects with a tool, wherein said at least one of said partial opening or said partial shape is offset from an axis of said threaded portion.

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